

This letter provides a reference to the Department's rules regarding food, drugs, medicines and medical appliances. See 86 Ill. Adm. Code 130.310. (This is a GIL.)

January 4, 2007

Dear Xxxxx:

This letter is in response to your letter dated October 9, 2006, in which you request information. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at www.ILTAX.com to review regulations, letter rulings and other types of information relevant to your inquiry.

The nature of your inquiry and the information you have provided require that we respond with a GIL. In your letter you have stated and made inquiry as follows:

My client is a manufacturer and retailer of a medical birth control device. This medical device is a new form of permanent birth control which is designed to provide an alternative to incisional methods of tubal ligation for women seeking permanent contraception.

The permanent birth control device is surgically implanted

The permanent birth control system consists of a micro-insert, a disposable delivery system, and a disposable split introducer. The micro-insert consists of a stainless steel inner coil, a nitinol, superelastic outer coil, and polyethelene terephthalate (PET) fibers. The disposable delivery system consists of a single-handed ergonomic handle which contains a delivery wire, release catheter, and delivery catheter.

Using a hysteroscope, a gynecologist places one micro-insert in the proximal section of each fallopian tube lumen. When the micro-insert expands upon release, it remains anchored in the fallopian tube and results in permanent birth control.

The birth control device has received Federal Food and Drug Administration Approval

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has approved the device for commercial distribution under the following conditions:

1. The sale, distribution, and use of this device is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of sections 520(e) of the Federal Food, Drug, and Cosmetic Act
2. To ensure the safe and effective use of the device, professional labeling must specify the training requirement of practitioners who may use the device and
3. The sales, distribution, and use must not violate sections 502(q) and (r) of the act

Instructions For Use

IMPORTANT

- Caution: Federal law restricts this device to sale by or on the order of a physician. This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the training program. Completion of the Training Program includes preceptoring the product in placement until competency is established, which is typically expected to be achieved in 5 cases.

IMPORTANT

- The micro-inserts should NOT be relied on for contraception until the patient has undergone a hysterosalpingogram (HSG) 3 months after micro-insert placement, which demonstrates **both** bilateral tubal occlusion **and** satisfactory location of the micro-inserts.
- If micro-inserts cannot be placed bilaterally, then the patient should not rely on this method of sterilization. This product has not been proven to be effective when it is placed unilaterally.
- This product is intended to prevent pregnancy. It does not protect against either HIV infection or other sexually transmitted diseases

Women chose permanent birth control for health reasons

According to the Center for Disease Control and Prevention (CDC), an unintended pregnancy is a significant public health issue that affects not only the woman's health but also the health of the newborn infant and society as a whole. Many women are not healthy enough to risk an unintended pregnancy and may develop a serious disease as a result. For example, some pregnant women are vulnerable to detrimental health conditions such as hypertension, diabetes and heart disease.

More than one in three pregnant women in the U.S. develop a pregnancy-related complication and two or three women die every day from these pregnancy related complications. The risks of pregnancy related deaths rise after the age of 35. By the age of 40, pregnancy-related risks for women rise as much as 50 times higher than women in their twenties. Although teenagers have the highest rate of unintended pregnancy, the second highest rate is found in women aged 40-44.

Summary

It is well documented that an unintended pregnancy for a woman is a significant health issue. My client's product provides a safe and reliable alternative for women to achieve permanent contraception in order to protect their health and wellbeing. My client's product is restricted to prescription use by trained practitioners for permanent surgical implantation in the women's fallopian tube and this birth control procedure is not reversible. Since this procedure is used to achieve permanent birth control, the product will be used by older women to prevent an unwanted pregnancy and the related health complications.

Taxability of the permanent birth control device

Given that my client has nexus with your state and that my client's customers are located in your state, are the sales of the permanent birth control device described above subject to sales or use tax in your state?

DEPARTMENT'S RESPONSE

For useful information regarding the taxation of food, drugs, medicines and medical appliances, we refer you to the Department's regulation at 86 Ill. Adm. Code 130.310. Those products that qualify as medicines, drugs, or medical appliances are taxed at the reduced tax rate of 1% plus applicable local taxes. Those that do not qualify for the low rate are taxed at the State rate of 6.25%, plus applicable local taxes.

The definition of a medical appliance is "an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body." Please note that 86 Ill. Adm. Code 130.310(c)(2) provides that medical appliances may be prescribed by licensed health care professionals for use by a patient, purchased by health care professionals for the use of patients, or purchased directly by individuals. In addition, not all items prescribed by physicians or other licensed health care professionals qualify for the low rate. A medicine or drug is defined at Section 130.310(c)(1) as "any pill, powder, potion, salves, or other preparation intended by the manufacturer for human use and which purports on the label to have medicinal qualities."

Examples of items that qualify for the reduced rate are corrective medical appliances such as hearing aids, eyeglasses and contact lenses. As a general proposition, diagnostic, treatment, and rehabilitative equipment items do not qualify for the reduced rate of tax as medical appliances because such items are not "for use in directly substituting for a malfunctioning part of the body," 86 Ill. Adm. Code 130.310(c)(2).

You can determine the tax status of medical devices by applying the principles set forth in the regulation. Medical devices such as the one described in your letter do not generally qualify for the low rate of tax.

If you require additional information, please visit our website at www.ILTAX.com or contact the Department's Taxpayer Information Division at (217) 782-3336. If you are not under audit and you wish to obtain a binding PLR regarding your factual situation, please submit a request conforming to the requirements of 2 Ill. Adm. Code 1200.110 (b).

Very truly yours,

Martha P. Mote
Associate Counsel

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